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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,286	12/03/2003	Jutta Eigemann	821-011726-US(PAR)	6913
28501	7590	04/06/2006	EXAMINER	
MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877-0368			SCHELL, LAURA C	
			ART UNIT	PAPER NUMBER
			3767	
DATE MAILED: 04/06/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/727,286	Applicant(s) EIGEMANN ET AL.	
	Examiner Laura C. Schell	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/3/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17, drawn to a piston pumping system, classified in class 277, subclass 438.
- II. Claims 18-20, drawn to a medical device for pumping pharmaceuticals using a piston pumping system, classified in class 604, subclass 151.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require that the medical device have the specified dimensions of the subcombination. The subcombination has separate utility such as a piston pumping system used for pumping other materials such as water.

Applicant's election with traverse of subcombination of the piston pumping system during a provisional election over the phone on 3/21/06 is acknowledged. The traversal is on the ground(s) that group II is not a combination in relation to group I and that the inventions only differ in the preamble. This is not found persuasive because group I is piston pumping system which can be used in many different applications,

while group II is a medical device which incorporates the piston pumping system of group I, and therefore they are related as subcombination and combination.

The requirement is still deemed proper and is therefore made FINAL.

Claims 18-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the election over the telephone on 3/21/06.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the claimed "helical spring" in claim 11 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: page 12 of the specification discloses a "cord thickness of $d1=1.1\text{mm}$ ", however, this is not shown in the drawings. Examiner also requests that Applicant further define what a "cord thickness" is as it is unclear what the Applicant is intending to state. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as

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either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: page 12, lines 13-14 disclose "a groove with b1=1.1mm", however, the specification does not describe what "b1" is as it relates to the invention. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following claim recitations "means of a helical spring", "means of a microchip" and "means of a piezoelectric element" in claims 11, 13 and 14, respectively, are not considered as invoking 35 USC 112 6th paragraph as they do not meet the 3 prong test set forth in the MPEP 2181.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 8-10 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hobbs (US Patent No. 4,813,932) in view of Evans et al. (US Patent No. 6,409,175). Hobbs discloses a piston pumping system (Fig. 1a) comprising a piston

(7) within a guide tube (6) which is capable of performing a stroke movement along its longitudinal axis, opening into a pumping chamber (the area in Fig. 1 which boxes in the numbers "11" and "23"), the pumping chamber being connected via a liquid conveying connection (24) with valve (25) to a storage vessel (4) and from the pumping chamber a liquid conveying connection (the area that connects the funnel portion to the pumping chamber) leads to a device for delivering liquid (this connection leads to a funnel for delivering liquid (breast milk) from the breast to the pumping chamber), wherein the guide tube is formed an O-ring (11) seal held in a groove (Fig. 5, 10) which seals off the piston, wherein the O-ring is made of silicon (col. 2, lines 60-62) which inherently has a gas permeation coefficient of $100 \text{ to } 500 \text{ N}\cdot\text{cm}^3\cdot\text{mm}/(\text{m}^2\cdot\text{h}\cdot\text{bar})$ for nitrogen (N_2) as indicated in Applicant's disclosure on page 9. Hobbs further discloses that the piston pumping system uses a plug valve (Fig. 1a, 25) which is a type of non-return valve. Hobbs also discloses that the movement of the piston is mechanically controlled by the movement of the lever (9). Hobbs further discloses that the device for delivering liquid is an outlet (2).

Hobbs, however, does not expressly disclose that the radial compression of the seal is less than 30% or that the seal fills the groove at a level of more than 90%. Evans, however, discloses that O-ring seals that are compressed at either 10% or 20% (less than 30%) will fill the groove more than 90% (the percent of the groove not filled is either less than 10% or less than 9.5%, and hence the percentage filled is greater than 90% in both cases) as shown in Fig. 19. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Hobbs to specify

that an O-ring property includes that when it is compressed less than 30% fill a groove by more than 90%, as taught by Evans.

Claims 5-7, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hobbs in view of Evans, as applied to claim 1 above, and further in view of Rush et al. (US Patent No. 6,916,159). Hobbs in view of Evans discloses the device substantially as claimed except for the exact measurements of the piston pumping system. Rush, however, discloses a piston pumping system wherein the piston shaft has a diameter of 3.2 mm and therefore the diameter of the piston would be a similar size, and the piston has a length of 10 mm, both of which fall within range specified (col. 9, lines 18-19). Rush also discloses that the pump volume can be as small as 0.5-5 microliters (col. 3, line 5). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Hobbs in view of Evans with the size of the piston pumping system as taught by Rush, in order to make a smaller and more conveniently sized piston pumping system.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hobbs in view of Evans, as applied to claim 10 above, and further in view of Richter (US Patent No. 4,961,726). Hobbs in view of Evans discloses the device substantially as claimed except for using a helical spring to control the movement of the piston. Richter, however, discloses that a helical spring is used to control the movement of the piston in a piston pumping system (Fig. 1). Therefore it would have been obvious to one of ordinary skill in the art to have modified Hobbs in view of Evans, with the helical spring as taught by Richter in order to provide a spring that directly acts on the piston.

Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hobbs in view of Evans, as applied to claim 1 above, and further in view of Greter et al. (US Patent No. 6,547,756). Hobbs in view of Evans discloses the device substantially as claimed, except for the piston pumping system being controlled electronically. Greter, however, discloses a piston pumping systems that is controlled electronically by a microprocessor, which inherently has a microchip (Figs. 9 and 10). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Hobbs in view of Evans with an electronically controlled system as taught by Greter, in order to provide a piston pumping system that can be controlled precisely and automatically.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mayfield (US Patent No. 4,468,221) discloses a piston pumping system with O-ring seal, a pumping chamber being connected to a storage vessel, and also connected to a device for delivering liquid, and also has check valves.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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KEVIN SIRMONS
PRIMARY EXAMINER

Kevin C. Sirmons